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| 26815 | 7590 | 10/09/2003 | EXAMINER | |
| JAYADEEP R. DESHMUKH RANBAXY PHARMACEUTICALS INC. 600 COLLEGE ROAD EAST SUITE 2100 PRINCETON, NJ 08540 | | | MCKENZIE, THOMAS C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | 13 |
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/051,784

Applicant(s)

MEHTA ET AL.

Examiner

Thomas McKenzie, Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-26 and 28-38 is/are rejected.
- 7) ☒ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5&7. 6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to amendments and an election filed on 9/25/03. Applicant has canceled claims 1-16. Claims 25-38 are new. There are twenty-five claims pending and twenty-five under consideration. Claims 25-27 are compound claims. Claims 28 and 29 are composition claims. Claim 30 is a method of using claim. Claims 16-24 and 31-38 are method of making claims. This is the first action on the merits. The application concerns some piperazinyl linked oxazolidinone compounds, compositions, and uses thereof.

Title

2. The title of the invention is not descriptive after restriction. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: addition of the word "Piperazinyl" before derivatives.

Abstract

3. Applicant is reminded of the proper content of an abstract of the disclosure. A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." The

abstract is too short and generic. Examiner suggests claim 25, including the figure, and the utility.

Priority

4. It is noted that this application claims subject matter disclosed in prior Application No. 09/906,215, filed 7/16/01. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of

four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Objections

5. Claim 27 is objected to because of the following informalities: the Examiner has seen the printer confuse compounds numbers "28." etc with claim numbers.

The examiner suggests removing all the extra number from this claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 25, 31, and 33, ring T is described as a “five to seven membered heterocyclic ring”. The word “heterocyclic” is not defined in the specification and is indefinite. What is the nature of this ring? All the word “heterocyclic” implies that at least one ring is involved and at least one member of this ring is not a carbon atom. What atoms are permitted? Are the atoms limited to oxygen, nitrogen, and sulfur or is phosphorus, silicon, a metal, or a halogen permitted? What is the nature of the bonding? How many rings can there be, only one or are fused and bridged rings also allowed? Must the ring be unsaturated and aromatic or are saturated rings also allowed?

7. Claims 25 and 28-30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. In the definition of variable R is claim 25, Applicants list "halogen-CN". This is, in fact, a compound. Was halogen, CN intended?

8. Claims 26 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 26 the phrase "heteroaryl except $M = S$, $Q = P = H$, $W = (CO)$ " occurs. This is in a definition of variable R_{11} that does not contain W, Q, or P. It appears to be a proviso but it is not clear to the Examiner what is being excluded. Does it mean when $M = S$, then $Q = P = H$ and $W = (CO)$? Does it mean when $M = S$ and $Q = P = H$, then $W = (CO)$? Or must M always = S, Q = P always = H, and W always = (CO)?

9. Claims 26 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 26 the phrase "heteroaryl except $W = (CO)$, Q and $P = H$ and $M = S$, wherein M = Sulphur and Oxygen", occurs. This is in a definition of variable R_{10} that does not contain W, Q, or P. It appears to be a proviso but it is not clear to the Examiner what is being excluded. Does it mean when $W = (CO)$, then $M = S$ and $Q = P = H$? Does it mean when $Q = P = H$ and $W = (CO)$, then $M = S$? Or must M always = S, Q = P always = H,

and W always = (CO)? Are only formulas III and IV being claimed or is Formula II claimed as well? Can M ever be NH or N-CH₃?

10. Claims 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 34 and 39 the phrase "heteroaryl except W = (CO), Q and P = H and M = S, wherein M = Sulphur", occurs. This is in a definition of variable R₁₀ that does not contain W, Q, or P. It appears to be a proviso but it is not clear to the Examiner what is being excluded. Does it mean when W = (CO), then M = S and Q = P = H? Does it mean when Q = P = H and W = (CO), then M = S? Or must M always = S, Q = P always = H, and W always = (CO)? Is only formula III being claimed or is Formula II claimed as well? Can M ever be NH or N-CH₃? Must it always be sulfur?

11. Additionally in claim 34 the phrase is followed by a period in the middle of the sentence.

12. Additionally in claim 39, M is restricted to sulfur in formula III but in the next to last line it is defined as "the same as defined earlier". Is this earlier in claim 39? Must M be sulfur?

13. Claims 34-38 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. Formula VI in claim 34 contains variable R_{12} . Formula V in claim 34 contains the variable G. Claim 34 appears to be an independent claim but has no definition of either term.

14. Claim 36 recites the limitation "Formula VI is furaldehyde" in line 2. This requires $Q = P = \text{hydrogen}$, $R_{12} = \text{CHO}$, and $M = \text{oxygen}$. There is no antecedent basis for these limitations in claim 34. There are three issues. Firstly, R_{12} is undefined in the claim and cannot be CHO. Secondly, P and Q can be a number of radicals including CHO, but not hydrogen. Thirdly, claim 34 appears to limit M to be sulfur.

15. Claim 37 recites the limitation "Formula VI is furoic acid" in line 2. This requires $Q = P = \text{hydrogen}$, $R_{12} = \text{CO}_2\text{H}$, and $M = \text{oxygen}$. There is no antecedent basis for these limitations in claim 34. There are three issues. Firstly, R_{12} is undefined in the claim and cannot be CO_2H . Secondly, P and Q can be a number of radicals including CO_2H , but not hydrogen. Thirdly, claim 34 appears to limit M to be sulfur.

16. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the

same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 38 recites the broad recitation a compound of the formula VI, and the claim also recites "including N-methyl pyrrole" which is the narrower statement of the range/limitation.

17. Claim 38 recites the limitation " compound of Formula VI including N-methyl pyrrole" in line 3. This requires $Q = P = R_{12} = H$ and $M = N-CH_3$. There is no antecedent basis for these limitations in claim 34. There are three issues. Firstly, R_{12} is undefined in the claim and cannot be H. Secondly, P and Q can be a number of radicals but not hydrogen. Thirdly, claim 34 appears to limit M to be sulfur.

18. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “R₁₄ is any group which can be converted to group R₁₅ in one to five steps” is a product by process claim. Yet Applicants do not tell us the reagents, specific solvents, temperatures, reaction times, catalysts, pressures, reaction types, and reagents Applicants intending for their process. Thus, we cannot determine what is the product this multi-step process.

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. Where does linker W in formulas II and III come from? It is not present in the two reagents used to make formulas II and III. The catalyst and the reagent that supplies linker W critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The two reagents linked to form FORMULA II are FORMULA V and FORMULA VI. Variable G in FORMULA V drawn to piperazines must be NH. Turning to pages 20-23 to better understand Applicants intent, there are three synthetic methods,

only method A uses a suitable R_{12} group as the Examiner understands the term. Line 1, page 20 says, " R_{12} is a suitable leaving group". The paragraph spanning pages 20-21 teaches two general procedures one with phosgene and the other with carbon monoxide. However, the phosgene reaction does not involve any kind of leaving group on FORMULA VI. The only process, which meets all the limitations of Applicants' claim, is the one with carbon monoxide and $Pd(PH_3)_2Cl_2$ as catalyst. Thus, these reagents are required for Applicants' process.

20. Claims 25, 26, 28-35, and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for synthesis of molecules with $W = CH_2$, $C(O)$, $-C(O)-C(O)-$, and $CH_2(CO)$, does not reasonably provide enablement for all the other claimed linker groups. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

"The factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*,

230 USPQ 546. a) Preparing any particular compound will require coupling the two pieces Formula V and Formula VI, thereby forming the linking group W. Considering the number of potential substituents upon the reagents and the number of linking groups, this is a large degree of experimentation. b) The direction concerning the synthesis was discussed in the preceding point. Use of carbon monoxide will give linker CO. Use of oxalyl chloride will give linker -C(O)-C(O)-. Reduction of the CO linker will give CH₂. Use of method C of page 22 with aryl acetic acids will give linker CH₂(CO). There is no direction indicated for linkers containing either nitrogen or sulfur. c) There are seventeen working examples of synthesis of compounds with W = CO found on pages 42-47, and 52-54. There are thirteen working examples of synthesis of compounds with W = CH₂ found on pages 47-52. There are no working examples of synthesis of any compound with linkers -C(O)-C(O)- and CH₂(CO). d) The nature of the invention is chemical synthesis, which involves chemical reactions. e) The state of the art is no methods are known for the synthesis of compounds with Applicants claimed nitrogen or sulfur linkers. f) The artisan using Applicants invention to prepare the claimed compounds would be a process chemist or pilot plant operator with a BS degree in chemistry and several years of experience. g) Chemical reactions are well-known to be unpredictable, *In re Marzocchi*, 169 USPQ 367, *In re Fisher*, 166 USPQ 18.

h) The breadth of the claims includes all of the thousands of compounds of formulas I< II, III, and IV.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

Claim Rejections - 35 USC § 102

21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

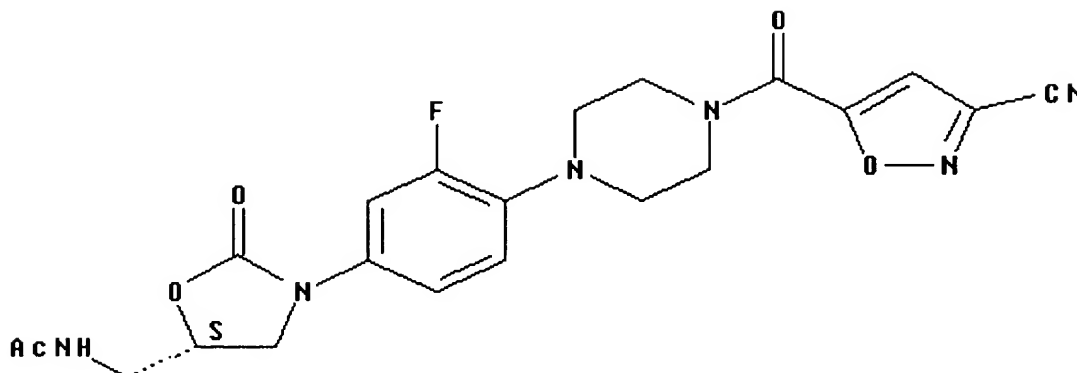
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 25, 31, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Pae (Bioorg. Ref C5). Six compounds in this reference anticipate Applicants' claims. The compound shown below with registry number 251913-04-9 fits



formula I with $R = \text{CN}$, $T = \text{isoxazole}$, $W = \text{C(O)}$, $U = \text{hydrogen}$, $V = \text{fluorine}$, and $R_1 = \text{NHC(O)CH}_3$, with $R_2 = \text{methyl}$. Applicants' claim 7 requires synthesis from a compound $R\text{-T-W-R}_{12}$ that is taught by the Friedel-Crafts reaction, method A in Scheme 1, page 2680. The compound is 8f and is found in Table 1 on page 2681 of the reference. Other anticipatory compounds are 6k, 8b, 8g, 8i, and 8o. Applicants' claim 32 requires a reductive amination synthesis. That is taught in the synthesis of 6k by route i) in Scheme 1, page 2680.

Claim Rejections - 35 USC § 103

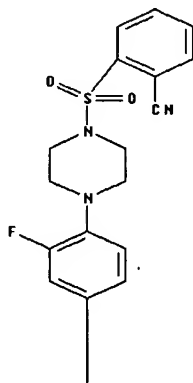
22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

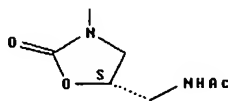
Claims 25 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gadwood ('985). The reference teaches the compound with registry number 189038-61-7 shown below. The Applicant claims the compounds I with $R = \text{CN}$, $T = \text{benzene}$, $W = \text{S}$, $U = \text{hydrogen}$, $V = \text{fluorine}$, and $R_1 = \text{NHC(O)CH}_3$, with $R_2 = \text{methyl}$. The reference teaches a compound with $W = \text{SO}_2$. The compound shown

in the reference in lines 40-48, column 13. Compositions and treatment of microbial infections is taught in lines 16-26, column 16. The difference between the claimed and taught compounds is the oxidation state of the sulfur linker. Applicants claim the reduced sulfide linker S and the reference teaches the oxidized sulfone linker SO₂. Sulfides are commonly metabolized to sulfones *in vivo*. It would be obvious to the skilled medicinal chemist, in view of the occurrence of cytochrome P450 and flavin-containing monooxygenase enzymes in the human liver to prepare such an oxidized metabolite from Applicants' compound. This would be expected to be a more stable active metabolite. The synthesis of the taught compound from the sulfonyl chloride makes obvious Applicants claim 31, which requires synthesis from a compound R-T-W-R₁₂. The leaving group R₁₂ taught in the prior art is chloride.

PAGE 1-A



PAGE 2-A



Double Patenting

23. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention", in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 16-24 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 16-24 of copending Application No. 09/906,215. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.


Conclusion

24. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for amendments is (703) 872-9306. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, you can reach the Examiner's

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supervisor, Mukund Shah at (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.


Thomas C. McKenzie, Ph.D.
Patent Examiner
Art Unit 1624

TCMcK

